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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,593	03/07/2005	Orhun K Muratoglu	49931-0102	2838

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EXAMINER	
HAUTH, GALEN H	

ART UNIT	PAPER NUMBER
1791	

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04/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,593	MURATOGLU ET AL.	
	Examiner	Art Unit	
	GALEN HAUTH	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,12,15,16,43,47,48,59-61,140-146 and 174-176* is/are pending in the application.

4a) Of the above claim(s) *140-146 and 174-176* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12,15,16,43,47,48,59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/13/2009 has been entered.

Response to Amendment

2. Acknowledgement is made to applicant's amendment of claims 1, 43, 59, and 60. No new matter has been added.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-4, 6, 12, 15, 16, and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al. (PN 5879400) in view of Ashby et al. (PN 5989472).

a. With regards to claim 1, Merrill teaches a method for forming a medical prosthesis for use in the body of ultra high molecular weight polyethylene (abstract) in which a fabricated polyethylene article is irradiated using electron irradiation while at a temperature above the melting temperature (col 2 ln 30-50) to reduce the free radicals in the article and crosslink the article (col 11 ln 27-29, col 7 ln 6-7). Merrill does not teach that the initial fabricated polyethylene article is compression molded to another piece.

b. Ashby teaches a method for forming prosthetic component in which a metal backing is molded to a polymeric substance in which the metallic grill is embedded within the plastic material (abstract). Ashby teaches compression molding the metallic piece to ultra high molecular weight polyethylene powder to provide an excellent mechanical lock between the two parts (col 3 ln 5-13, the lock being the interface). It would have been obvious to one of ordinary skill in the art at the time the invention was made to compression mold a ultra high molecular weight polyethylene article taught by Merrill to a wire mesh as taught by Ashby, because Ashby teaches that the mesh is intended to provide ingrowth (col 3 ln 24-25) and both teach using ultra high molecular weight polyethylene for implants in hips and knees (col 3 ln 28-33 in Ashby, col 1 ln 14-15 in Merrill) and provides and excellent mechanical lock between the two parts (col 3 ln 5-13).

Merrill teaches that the polymeric substance used can be a machined or molded article (col 6 ln 12), so it would have been obvious to one of ordinary skill in the art at the time the invention was made to compression mold the mesh taught by Ashby to the polyethylene while molding to shape the implant article, because doing so increases the efficiency of the process by using one molding step and provides an excellent mechanical lock between the two parts (col 3 ln 5-13 of Ashby). The claim as it stands reads on simultaneous heating and irradiation of the polyethylene.

c. With regards to claim 2, Ashby (col 3 ln 5) and Merrill (col 2 ln 32) teach using a polyethylene powder, and Ashby teaches that the polyethylene is compression molded to the metallic back (col 3 ln 5-13).

d. With regards to claim 3, Ashby teaches that the metallic back serves to provide ingrowth or to be in contact with cement (col 3 ln 24-27).

e. With regards to claim 4, Merrill teaches forming hip and knee joints (col 1 ln 14-15), and Ashby teaches forming patella, tibia, elbow, shoulder, and hip cup components (col 3 ln 28-33).

f. With regards to claim 6, Merrill teaches irradiating in a nitrogen inert environment (col 11 ln 56-57).

g. With regards to claim 12, Merrill teaches using a dose of 200 kGy (col 8 ln 37, 100 Rad is equal to 1 Gray, therefor 10 kGy is equal to 1 MRad, therefor 20 MRad is equal to 200 kGy).

h. With regards to claim 15, Ashby teaches using a metallic backing for use in a patella component (col 2 ln 44-45).

i. With regards to claim 16, Ashby teaches that the article comprises a metallic mesh (col 2ln 54-55).

j. With regards to claim 59, Merrill in view of Ashby teaches forming a composite article from compression molded ultra high molecular weight polyethylene powder with a metallic grid that is mechanically locked together (Ashby col 3 ln 3-13), irradiating the article to remove free radicals and crosslink (col 11 ln 27-29, col 7 ln 6-7) and heating the material above the melting temperature (col 2 ln 30-50) as described in the rejection of claim 1.

k. With regards to claim 60, Ashby teaches that the plastic and metal are mechanically locked together (col 3 ln 12-13).

l. With regards to claim 61, Merrill teaches that the article is sterilized (col 4 ln 42-44).

6. Claims 43 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al. (PN 5879400) in view of Ashby et al. (PN 5989472) and Johnson (PN 4971761)

a. With regards to claim 43, Merrill teaches a method for forming a medical prosthesis for use in the body of ultra high molecular weight polyethylene (abstract) in which a fabricated polyethylene article is irradiated using electron irradiation while at a temperature above the melting temperature (col 2 ln 30-50) to reduce the free radicals in the article (col 11 ln 27-29). The discussion of

Merrill and Ashby of ¶ 4(a,b) above is incorporated herein. Merrill teaches that the article is sterilized (col 4 ln 42-44). Merrill in view of Ashby does not teach that the initial fabricated polyethylene article is compression molded to another piece, as for an additional limitation the piece is sterilized using gas.

b. Johnson teaches that gas sterilization using ethylene oxide is a well established procedure for biological sciences and health care professions (col 1 ln 13-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to sterilize the hybrid article of Merrill in view of Ashby with gas as taught by Johnson, because such is an art recognized method of sterilization as taught by Johnson (col 1 ln 13-15, Johnson) and Merrill acknowledges providing a sterilization process (col 4 ln 42-44, Merrill). The claim as it stands reads on simultaneous heating and irradiation of the polyethylene.

c. With regards to claim 48, Merrill teaches that the article is heated in an inert environment of nitrogen, argon or helium (col 6 ln 53-58).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al. (PN 5879400) in view of Ashby et al. (PN 5989472) as applied to claim 1 above, and further in view of Kagiya et al. (PN 3894928).

a. Merrill in view of Ashby teaches a method for forming a cross-linked composite polyethylene article in which a metallic mesh is compression molded to polyethylene, irradiated and heated. Merrill in view of Ashby does not teach that the article is irradiated in an atmosphere containing 1% - 22% oxygen.

b. Kagiya teaches a method for cross-linking polyethylene through ionizing radiation (abstract) in which the radiation occurs in air (col 3 ln 5-6, air is 21% oxygen) in the presence of a small amount of acrylic monomer (col 1 ln 44-48) resulting in a article with excellent mechanical strength, and heat and chemical resistance (col 1 ln 18-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to irradiate the article of Merrill in view of Ashby in the air environment of Kagiya to produce and article with excellent mechanical strength, and heat and chemical resistance (col 1 ln 18-19).

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al. (PN 5879400) in view of Ashby et al. (PN 5989472) as applied to claim 1 above, and further in view of Patel (PN 4164458).

a. Merrill in view of Ashby teaches a method for forming a cross-linked composite polyethylene article in which a metallic mesh is compression molded to polyethylene, irradiated, heated. Merrill in view of Ashby and Johnson does not teach that the article is irradiated in an atmosphere containing 1% - 22% oxygen.

b. Patel teaches a method for producing cross-linked polymer articles by subjecting thermoplastic cross-linkable polymers mixed with diacetylene to actinic radiation (abstract) in which polyethylene is irradiated with 1 MRad of gamma radiation at room temperature in air followed by heating the article in air to decay trapped free radicals (col 7 ln 58-62, air is 21% oxygen). It would have been obvious to one of ordinary skill in the art at the time the invention was made

to subject the article of Merrill in view of Ashby and Johnson to irradiation in air as taught by Patel as such is an art recognized technique for effective cross-linking of polyethylene articles.

9. Claim 47 rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al. (PN 5879400) in view of Ashby et al. (PN 5989472) and Johnson (PN 4971761) as applied to claim 43 above, and further in view of Patel (PN 4164458).

a. Merrill in view of Ashby and Johnson teaches a method for forming a cross-linked composite polyethylene article in which a metallic mesh is compression molded to polyethylene, irradiated, heated, and sterilized. Merrill in view of Ashby and Johnson does not teach that the article is heated in an atmosphere containing 1% - 22% oxygen.

b. Patel teaches a method for producing cross-linked polymer articles by subjecting thermoplastic cross-linkable polymers mixed with diacetylene to actinic radiation (abstract) in which polyethylene is irradiated with 1 MRad of gamma radiation at room temperature in air followed by heating the article in air to decay trapped free radicals (col 7 ln 58-62, air is 21% oxygen). It would have been obvious to one of ordinary skill in the art at the time the invention was made to subject the article of Merrill in view of Ashby and Johnson to heating in air as taught by Patel as such is an art recognized technique for effective cross-linking of polyethylene articles.

Claim Objections

10. Claim 3 is objected to for improper antecedent basis. Claim 3 recites the limitation of "the metallic back", but is dependent on claim 1 in which no metallic back has been established. It is believe that this claim should be dependent on claim 2 for proper antecedent basis. Appropriate correction is required.

Response to Arguments

11. Applicant's arguments filed 02/13/2009 have been fully considered but they are not persuasive.

a. With regards to applicant's arguments that none of the references teach compression molding of polyethylene powder to a piece, Ashby teaches as cited above compression molding polyethylene powder to a metal component (col 3 ln 3-8).

b. With regards to applicant's argument that none of the references teach or suggest irradiation and heating of the hybrid material, Merrill teaches as cited above a method for forming a medical prosthesis for use in the body of ultra high molecular weight polyethylene (abstract) in which a fabricated polyethylene article is irradiated using electron irradiation while at a temperature above the melting temperature (col 2 ln 30-50).

c. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

d. With regards to applicant's arguments that combinations of Ashby, Merrill, Johnson, Kagiya, and/or Patel are not supported and are improper hindsight, Ashby and Merrill are both related to medical prosthesis production from polyethylene, while Merrill, Johnson, Kagiya, and Patel relate to crosslinking, processing, and sterilization of polyethylene components. All combinations are cited above with reasons for combining.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALEN HAUTH whose telephone number is (571)270-5516. The examiner can normally be reached on Monday to Thursday 8:30am-5:00pm ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571)272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GHH/

/Christina Johnson/
Supervisory Patent Examiner, Art Unit 1791